Supreme Court, U.S.
FILED
AUG 24 2010
OFFICE OF THE CLERK

No. 10-287

In the
Supreme Court of the United States

INNOVATIVE THERAPIES, INC.,
Petitioner,

v.

KINETIC CONCEPTS, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

Jonathan G. Graves
Counsel of Record
Justin P.D. Wilcox
Scott A. Cole
COOLEY LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive, Suite 1600
Reston, VA 20190
(703) 456-8000
jgraves@cooley.com

Attorneys for Petitioner

August 24, 2010

Becker Gallagher · Cincinnati, OH · Washington, D.C. · 800.890.5001

QUESTIONS PRESENTED

1. Whether Article III's grant of jurisdiction of "all Cases ... arising under ... the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), requires a patentee to direct an affirmative act toward a potential infringer for declaratory judgment subject matter jurisdiction to exist.

2. Whether Article III's grant of jurisdiction of "all Cases ... arising under ... the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), requires that a patentee be able to sue a potential infringer before declaratory judgment subject matter jurisdiction can exist.

3. What are the metes and bounds of a district court's discretion to dismiss a declaratory judgment complaint under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), despite the existence of an actual controversy.

PARTIES TO THE PROCEEDING

Petitioner Innovative Therapies, Inc. was the only appellant in the court below. Respondents Kinetic Concepts, Inc., KCI Licensing, Inc., and KCI USA, Inc. were the appellees in that court.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, petitioner states as follows:

Petitioner Innovative Therapies, Inc. is a privately held corporation. No publicly held entity owns 10% or more of its stock.

TABLE OF CONTENTS

PAGE

QUESTIONS PRESENTED i

PARTIES TO THE PROCEEDING ii

CORPORATE DISCLOSURE STATEMENT ii

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES vii

I. INTRODUCTION 1

II. OPINIONS BELOW 3

III. STATEMENT OF THE BASIS FOR JURISDICTION 3

IV. CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED IN THIS CASE ... 4

V. STATEMENT OF THE CASE 5

A. Background 5

1. ITI's Negative Pressure Wound Therapy System 5

2. ITI Receives FDA Approval and Offers the Svedman™ System for Sale. 6

3. KCI Makes Clear That It Will Aggressively Assert Its Intellectual Property Rights Against ITI. 8

4. KCI Documents Underscore the Significance of Girouard's and Burke's Statements. 10

B. The District Court Proceedings 10

C. Court of Appeals Decision 12

VI. REASONS FOR GRANTING THE WRIT . . . 13

A. A Patentee Need Not Direct an Affirmative Act Toward a Potential Declaratory Judgment Plaintiff for Declaratory Judgment Subject Matter Jurisdiction to Exist Under Article III or the Declaratory Judgment Act. 13

1. This Court Rejected the "Reasonable Apprehension of Suit" Test, Which Included an Affirmative Act Requirement. 13

2. The "Affirmative Act" Test Contravenes the "All the Circumstances" Standard For Determining Whether a Case or Controversy Exists. 15

3. The Federal Circuit's Affirmative Act Rule Conflicts with Other Circuits' Correct Application of the Declaratory Judgment Subject Matter Jurisdiction Jurisprudence of this Court. 18

B. *MedImmune* and Its Predecessors Make Clear that an Actual Controversy Exists Even If a Patentee Purportedly Could Not Have Sued the Declaratory Judgment Plaintiff 22

C. District Courts Do Not Have Unfettered Discretion to Dismiss Declaratory Judgment Actions Where an Actual Controversy Exists 24

VII. CONCLUSION 28

APPENDIX

Appendix A: Opinion, United States Court of Appeals for the Federal Circuit (April 1, 2010) 1a

Appendix B: Memorandum Order, In the United States District Court for the District of Delaware (November 5, 2008) 17a

Appendix C: Report and Recommendation Regarding Defendants' Motion to Dismiss, In the United States District Court for the District of Delaware (July 14, 2008) 22a

Appendix D: Order denying rehearing, United States Court of Appeals for the Federal Circuit (May 26, 2010) 44a

TABLE OF AUTHORITIES

PAGE

CASES

Aetna Cas. & Sur. Co. v. Quarles,
92 F.2d 321 (4th Cir. 1937) 25

Aetna Life Ins. Co. v. Haworth,
300 U.S. 227 (1937) 23

Brillhart v. Excess Ins. Co.,
316 U.S. 495 (1942) 25

Dewey & Almy Chem. Co. v. Am. Anode, Inc.,
137 F.2d 68 (1943) 19

Hulteen v. AT&T Corp.,
498 F.3d 1001 (9th Cir. 2007) (en banc), *rev'd on other grounds*, 129 S. Ct. 1962 (2009) 20, 21

Maryland Cas. Co. v. Pac. Coal & Oil Co.,
312 U.S. 270 (1941) 16, 18, 19, 20, 21, 23

MedImmune, Inc. v. Genentech, Inc.,
549 U.S. 118 (2007) . . 1, 2, 11, 12, 13, 14, 15, 16, 18, 21, 22, 23, 24, 26

Micron Tech., Inc. v. Mosaid Techs., Inc.,
518 F.3d 897 (Fed. Cir. 2008) 25, 27

NBA v. SDC Basketball Club, Inc.,
815 F.2d 562 (9th Cir. 1987) 21

Pub. Affairs Assocs., Inc. v. Rickover,
369 U.S. 111 (1962) 25, 26

Pub. Serv. Comm'n v. Wycoff Co.,
344 U.S. 237 (1952) 25

SanDisk Corp. v. STMicroelectronics, Inc.,
480 F.3d 1372 (Fed. Cir. 2007) 11, 12, 13

Teva Pharm. USA, Inc. v. Pfizer, Inc.,
395 F.3d 1324 (Fed. Cir. 2005) 14

Venator Group Specialty, Inc. v. Matthew/Muniot Family, LLC,
322 F.3d 835 (5th Cir. 2003) 20

Wilton v. Seven Falls Co.,
515 U.S. 277 (1995) 24

Yahoo! Inc. v. La Ligue Contre Le Racisme Et L'Antisemitisme,
433 F.3d 1199 (9th Cir. 2006) (per curiam) .. 21

CONSTITUTION

U.S. Const. art. III, § 2 ..... *passim*

STATUTES

28 U.S.C. § 1254(1) 3

28 U.S.C. § 2201(a) ..... i, 2, 4, 24

OTHER AUTHORITIES

Brief for United States Amicus at 15-16, *MedImmune, Inc. v. Genentech Inc.* (May 2006) (No. 05-608) 14

Henry J. Friendly, *Indiscretion About Discretion*, 31 Emory L.J. 747 (1982) 27

Senate Report No. 1005, 73d Cong., 2d Sess. (May 10, 1934) 25

I.
INTRODUCTION

This case presents fundamental questions of declaratory judgment subject matter jurisdiction and the faithful application of this Court's precedents by the United States Court of Appeals for the Federal Circuit ("Federal Circuit"). The Federal Circuit has once again departed from this Court's precedents regarding declaratory judgment subject matter jurisdiction, creating a new rule that requires a patentee to direct an "affirmative act" toward a potential infringer before that potential infringer may bring a declaratory judgment action to clarify its rights regarding the patents-in-question. This Court recently rejected such a formulaic rule for declaratory judgment subject matter jurisdiction. In *MedImmune, Inc. v. Genentech, Inc.*, this Court reconfirmed the time-tested threshold for establishing subject matter jurisdiction in declaratory judgment actions: "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." 549 U.S. 118, 127 (2007). In so doing, the Court specifically rejected the Federal Circuit's "reasonable apprehension of suit" test. *Id.* at 132 n.11. Here, the Federal Circuit improperly resurrected the "reasonable apprehension of suit" test through the "affirmative act" rule in direct contravention of *MedImmune*.

This case also presents an issue that this Court has not directly addressed: what are the metes and bounds of a district court's discretion to dismiss a declaratory judgment action involving a patent dispute

where an actual controversy exists? Here, the Federal Circuit affirmed the District Court's discretionary dismissal, focusing solely on whether the pre-suit conduct of petitioner Innovative Therapies, Inc. ("ITI") comported with the objectives of the Declaratory Judgment Act. The Federal Circuit should have instead analyzed whether hearing the case would serve the objective for which the Declaratory Judgment Act was created—relieving the Damoclean threat of suit. Here, there can be no doubt that ITI faced the Damoclean threat of suit from a highly litigious corporation that had sued every competitor with a commercially-viable product.

Now that *MedImmune* has arguably lowered the threshold for establishing an actual controversy sufficient to establish declaratory judgment subject matter jurisdiction, the exercise of discretionary dismissals, such as here, will likely become more common as the number of filed declaratory judgment actions expands. However, unfettered discretionary dismissals would frustrate the objectives of the Declaratory Judgment Act by leaving potentially infringing entities no recourse but to wait for a patentee to sue at the time and place of its choosing.

This Court should grant certiorari to correct the Federal Circuit's application of *MedImmune* and declaratory judgment subject matter jurisdiction principles, and to clarify the discretion of district courts under 28 U.S.C. § 2201(a) to dismiss declaratory judgment actions despite the existence of an actual controversy.

II.
OPINIONS BELOW

The opinion of the Federal Circuit is reported at 599 F.3d 1377 and is reproduced in the Appendix at 1a.[1] The order denying the petition for rehearing en banc is unreported. 44a. The memorandum order of the district judge of the District Court for the District of Delaware was unreported. 17. The report and recommendation of the magistrate judge of the District Court for the District of Delaware was unreported. 22a.

III.
STATEMENT OF THE BASIS FOR JURISDICTION

This Court has jurisdiction over this petition under 28 U.S.C. § 1254(1) because the petition asks the Court to issue a writ of certiorari to review a decision of the United States Court of Appeals for the Federal Circuit. The Court of Appeals issued its decision on April 1, 2010. 1a. The Court of Appeals denied ITI's petition for rehearing en banc on May 26, 2010. 44a. This petition is being filed with the Clerk of this Court within 90 days from the date of the denial of the petition for rehearing en banc.

---

[1] Citations to "a" are to the appendix to this petition. Citations to "C.A.A." are to the joint appendix filed in the Federal Circuit.

IV.
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED IN THIS CASE

Article III Section 2 of the United States Constitution provides in pertinent part:

> The judicial power shall extend to all cases, in law and equity, arising under this Constitution, the laws of the United States, and treaties made, or which shall be made, under their authority;--to all cases affecting ambassadors, other public ministers and consuls;--to all cases of admiralty and maritime jurisdiction;--to controversies to which the United States shall be a party;--to controversies between two or more states;--between a state and citizens of another state;--between citizens of different states;--between citizens of the same state claiming lands under grants of different states, and between a state, or the citizens thereof, and foreign states, citizens or subjects.

28 U.S.C. § 2201(a) provides:

> (a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the

United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

V.
STATEMENT OF THE CASE

A. Background

1. ITI's Negative Pressure Wound Therapy System

Petitioner ITI, a start-up medical device company, designed and developed a negative pressure wound therapy ("NPWT")[2] device named the Svedman™ system to treat chronic wounds. Respondents Kinetic Concepts, Inc., KCI Licensing, Inc., and KCI USA, Inc. (collectively, "KCI") manufacture and sell a family of NPWT devices called the Vacuum Assisted Closure (V.A.C.®).

ITI's founders recognized a critical need for an affordable alternative to KCI's patented V.A.C.® NPWT devices. C.A.A.535. Because many health care facilities (such as nursing homes) cannot afford the significant cost of the V.A.C.®, thousands of patients in the United States do not receive the NPWT necessary

---

[2] NPWT involves the application of negative pressure to promote healing of chronic wounds typically through a combination of a vacuum and a pressure dressing.

to heal their chronic wounds, and in many cases, avoid amputation. C.A.A.535. ITI endeavored to offer the Svedman™ system at a substantial discount to the current market price for competitive products to meet the needs of patients with serious wounds who had previously been priced out of the NPWT market. C.A.A.535.

KCI has accumulated a portfolio of patents that it claims covers its V.A.C.® devices, including United States Patent Nos. 4,969,880 ("the '880 patent"), 5,645,081 ("the '081 patent"), 5,636,643 ("the '643 patent"), 7,198,046 ("the '046 patent"), and 7,216,651 ("the '651 patent) (collectively, "KCI patents"). C.A.A.332. KCI also claims that those patents broadly cover many other commercially available NPWT devices, and has a well-documented history of aggressively asserting its patent portfolio in litigation to limit competition with its V.A.C.® devices. From 2001 to 2007, KCI sued ten defendants in six different patent infringement lawsuits regarding NPWT devices. C.A.A.335. Those lawsuits included both of KCI's primary NPWT competitors in the chronic wound care treatment market: Medela and BlueSky Medical Corp./Smith & Nephew. C.A.A.335. Furthermore, KCI has even sued a doctor and hospitals that have dared to use NPWT technology other than KCI's V.A.C.® devices to treat patients with chronic wounds. C.A.A.483.

2. ITI Receives FDA Approval and Offers the Svedman™ System for Sale.

The FDA approved both of ITI's 510(k) submissions relating to the Svedman™ system. C.A.A.536. Those submissions took advantage of a FDA procedure that

streamlines the approval process by allowing an applicant to claim that its new medical device "has essentially the same technological characteristics" as a previously approved device, or "predicate device" in FDA lexicon. C.A.A.536-537. One of ITI's 510(k) submissions claimed one of KCI's V.A.C.® devices as a predicate device, asserting that the ITI device "has essentially the same technological characteristics as the previously cleared predicate device." C.A.A.536. The other 510(k) claimed as predicate devices for that 510(k) submission the Medela Invia™ Healing System and the BlueSky Medical Versatile 1™ Wound Vacuum System—both of which have been accused of patent infringement in other lawsuits filed by KCI. C.A.A.334, 536-537.

After receiving FDA approval, ITI proceeded to test the Svedman™ system through clinical evaluations in August 2007. C.A.A.536. During those evaluations, five patients with chronic wounds were successfully healed by the Svedman™ system, and the supervising physician provided testimonials regarding the outstanding chronic wound treatment provided by the Svedman™ system. C.A.A.536. As a result of the successful clinical evaluations, ITI decided to commercialize and market the Svedman™ system.

ITI made its first offer for sale of a Svedman™ system on September 27, 2007, and the first Svedman™ system was placed with a customer in the first week of October 2007. C.A.A.537.

3. KCI Makes Clear That It Will Aggressively Assert Its Intellectual Property Rights Against ITI.

Prior to offering the Svedman™ system for sale, Richard Vogel—ITI Chief Executive Officer and former KCI Vice President and Executive Committee member— and David Tumey—ITI's Chief Technology Officer and former KCI Director of Research & Development—decided to approach KCI regarding the Svedman™ system. As former KCI insiders, Vogel and Tumey had first hand experience with KCI's litigation decision-making process and tactics. C.A.A.509, 536. On the eve of their new company's launch of a device that would compete directly with KCI's V.A.C.® devices, they faced the almost certain prospect of being the next target of KCI's aggressive litigation tactics. C.A.A.509. Therefore, Tumey decided to contact some of his former colleagues at KCI to assess the potential for avoiding litigation by consummating a business relationship between the parties. C.A.A.510-511.

On September 12, 2007, Tumey called his former colleague, Michael Girouard, because he believed that, as KCI's Director of Marketing, Girouard would understand KCI's current institutional attitude toward patent enforcement against competitive products. C.A.A.510. During the call, Tumey asked Girouard if he was aware of the two 510(k) submissions filed by ITI that the FDA had recently approved. C.A.A.504, 507, 510, 526. Girouard replied that he was aware of one of the 510(k) submissions based upon discussions at KCI's regular "Competitive Intelligence" meetings. C.A.A.504-505, 510. Tumey explained to Mr. Girouard that his new company had been developing and was considering launching a chronic wound healing system

that utilized negative pressure and a polyurethane foam dressing. C.A.A.505, 510-511. When asked how he thought KCI might react to the introduction of such a product, Girouard responded, "KCI will act aggressively. You know that." C.A.A.505, 507, 510-511, 528.

On September 17, 2007, Tumey called KCI's Senior Vice President of Manufacturing, Michael Burke, a corporate officer and Executive Committee[3] member. Tumey called Burke—his former supervisor at KCI—to determine, as with Girouard, whether the parties could develop a business relationship regarding the Svedman™ system, and alternatively, to determine the litigation risk associated with launching the Svedman™ system. C.A.A.511.

Tumey explained to Burke that he was working on the launch of a new NPWT wound healing system utilizing polyurethane foam dressing, and asked Burke how he thought KCI would react to the release of such a product. C.A.A.511-512. Burke replied, "KCI will aggressively go after [you]", "particularly if it is foam-based." C.A.A.512, 530. When asked whether KCI and ITI could peacefully coexist regarding the Svedman™ system, Burke replied that there was "no way to coexist" and that it would not happen. C.A.A.512, 530. Tumey also queried Burke about the odds of a KCI suit if ITI launched the Svedman™ system; Mr. Burke replied that the odds were "very big" "100% no doubt about it," and that any product that "scratches the surface of [KCI's] patents" would be

---

[3] KCI is run by an Executive Committee comprised of approximately ten officers.

the subject of a lawsuit. C.A.A.512, 530. Burke concluded by warning Tumey to steer clear of a NPWT device that is foam-based. C.A.A.512, 530.

4. KCI Documents Underscore the Significance of Girouard's and Burke's Statements.

The significance of Messrs. Girouard's and Burke's statements was confirmed by pre-suit awareness documents belatedly produced by KCI in the district court proceedings. Those documents show that KCI was aware of both of ITI's 510(k) submissions prior to ITI's conversations with both gentlemen, and that those submissions were discussed at no fewer than seven KCI Competitive Intelligence meetings in the Spring and Summer of 2007. *See generally* C.A.A.1318, 1426, 1462-1463, 1533-1534, 1600-1601, 1625-1626. The documents also show that ITI's use of a foam dressing became the subject of a KCI investigation in which KCI's Senior Marketing Manager concluded that the use of foam dressings in conjunction with NPWT is covered by KCI's patent estate. C.A.A.763.

B. The District Court Proceedings

On September 25, 2010, two days before the commercial launch of its Svedman™ system, ITI filed a declaratory judgment complaint in the United States District Court for the District of Delaware, where ITI and two of the three KCI respondents are incorporated. C.A.A.37. ITI's Original Complaint sought declarations that the KCI patents are invalid and not infringed by ITI's first product. C.A.A.41-45. KCI filed a motion to dismiss the Original Complaint.

While its motion to dismiss the Delaware action was pending, KCI filed a patent infringement lawsuit against ITI in the District Court for the Middle District of North Carolina, claiming that the Svedman™ system infringes three of the KCI patents, and a Texas state court trade secret and business tort suit against ITI and its principals. ITI subsequently filed an Amended Complaint incorporating, *inter alia*, the facts of that patent infringement suit and KCI's Texas state court suit. KCI withdrew its original motion to dismiss and refiled a new motion to dismiss.

The Magistrate Judge issued a Report and Recommendation ("Report") on July 14, 2008, recommending that the District Court grant KCI's motion and dismiss ITI's declaratory judgment action. 22a. The Report examined this Court's decision in *MedImmune, Inc. v. Genentech Inc.*, 549 U.S. 118 (2007), and the Federal Circuit's subsequent application of that decision in *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1383 (Fed. Cir. 2007). 34a-35a. The Magistrate Judge seized upon the Federal Circuit's statement in *SanDisk* that "declaratory judgment jurisdiction generally will not arise ... without some affirmative act by the patentee" and concluded that the District Court lacked subject matter jurisdiction because ITI had not demonstrated any "affirmative act" by KCI towards ITI. 37a-38a.

ITI timely filed objections to the Magistrate Judge's Report. The District Court disagreed with the reasoning set forth in the Report, rejecting the notion that declaratory judgment jurisdiction cannot arise without an "affirmative act" by the patentee towards the declaratory judgment plaintiff. 21a. Nonetheless, the District Court exercised its discretion to grant

KCI's motion to dismiss the entirety of the Amended Complaint. *Id.* The District Court summarily concluded that the exercise of its jurisdiction would not serve the objectives of the Declaratory Judgment Act: "I am not convinced that the objectives of the Declaratory Judgment Act are being served by allowing such a plaintiff to plead uncertainty and delay." *Id.* The District Court accordingly dismissed ITI's declaratory judgment action and entered judgment for respondents. ITI appealed.

C. Court of Appeals Decision

The Federal Circuit, in an opinion by Judge Newman, joined by then-Chief Judge Michel and Judge Prost, affirmed the District Court's dismissal, applying the "affirmative act" jurisdictional rule announced in the *SanDisk* decision. 9a. According to that rule, "declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." *SanDisk*, 480 F.3d at 1380-81. The Federal Circuit held that the facts and circumstances of the case did not "meet the minimum standard discussed in *MedImmune*" "in the absence of any act directed toward ITI." 9a. The Federal Circuit also affirmed the District Court's discretionary dismissal. 12a (quoting District Court opinion).

VI.
REASONS FOR GRANTING THE WRIT

A. A Patentee Need Not Direct an Affirmative Act Toward a Potential Declaratory Judgment Plaintiff for Declaratory Judgment Subject Matter Jurisdiction to Exist Under Article III or the Declaratory Judgment Act.

In the wake of *MedImmune* and its rejection of the "reasonable apprehension of suit" standard for declaratory judgment subject matter jurisdiction, the Federal Circuit in *SanDisk* established a new rule for establishing such jurisdiction. Namely, the Federal Circuit held that "declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some ***affirmative act*** by the patentee." *SanDisk*, 480 F.3d at 1380-81 (emphasis added). In contravention of *MedImmune*, the Federal Circuit erroneously applied the "affirmative act" test in this case, concluding that the facts and circumstances of the case did not "meet the minimum standard discussed in *MedImmune*" "in the absence of any act directed toward ITI." 9a.

1. This Court Rejected the "Reasonable Apprehension of Suit" Test, Which Included an Affirmative Act Requirement.

In creating the "affirmative act" test, the Federal Circuit erroneously sought to resurrect the "reasonable apprehension of suit" test under a different moniker,

ignoring this Court's unambiguous rejection of that test in *MedImmune*. Indeed, the Federal Circuit previously required an affirmative act to satisfy the "reasonable apprehension of suit" test: "***an explicit threat or other action by the patentee*** which creates a ***reasonable apprehension*** on the part of the declaratory judgment plaintiff that it will face an infringement suit." *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1332 (Fed. Cir. 2005) (emphases added). This Court in *MedImmune* not only rejected the "reasonable apprehension" test itself, but also the very formulation of the test enunciated in *Teva* that required an affirmative act. 549 U.S. at 132 n.11 (rejecting both the "reasonable apprehension of suit" test and what it called the "'reasonable apprehension of imminent suit' test [of] *Teva*") (citation omitted). Thus, the Federal Circuit's use of the "affirmative act" test in this case flies in the face of this Court's clear rejection of that requirement in *MedImmune*.

The Federal Circuit's application of an "affirmative act" test also conflicts with the United States' position in its Amicus Brief supporting the petitioner in *MedImmune*. The United States argued that the "reasonable apprehension of suit test" through its "overt act or other action by the patentee" requirement improperly required "the declaratory judgment plaintiff [to] already have taken steps that expose it to a risk of suit," "impermissibly limit[ing] the broad power of the federal courts to hear and decide concrete disputes between adverse parties in appropriate declaratory judgment actions." United States Amicus Br. at 15-16, *MedImmune, Inc. v. Genentech Inc.*, No. 05-608 (May 2006). Indeed, the Federal Circuit's application of the "affirmative act" test plainly subjects ITI and future declaratory judgment plaintiffs to the

Hobson's choice about which the United States warned. ITI was acutely aware of KCI's litigious history in the NPWT field and had already been warned by senior KCI decision-makers that KCI would sue if ITI launched its NPWT product. Yet under the Federal Circuit's ruling, ITI could not properly seek a declaratory judgment unless and until it received a letter from KCI's president or general counsel expressly threatening litigation. 7a ("these informal conversations did not constitute a threat of suit"). Waiting for such an affirmative act would needlessly expose ITI and other similarly situated declaratory judgment plaintiffs to the risk of suit and prevent federal courts from adjudicating actual controversies.

In short, the Federal Circuit's application of an "affirmative act" test contravenes the *MedImmune* Court's rejection of the "reasonable apprehension of suit" test.

2. The "Affirmative Act" Test Contravenes the "All the Circumstances" Standard For Determining Whether a Case or Controversy Exists.

The "affirmative act" rule also conflicts with this Court's rejection of rigid and formulaic jurisdictional tests in *MedImmune*. This Court made clear that the reasonable apprehension of suit standard was overly restrictive and thus inconsistent with the standards for Article III jurisdiction and the historical purpose of the Declaratory Judgment Act—to provide a challenger with an alternative to the Hobson's choice between "abandoning his rights or risking prosecution." *MedImmune*, 549 U.S. at 129-34; *see also id.* at 129 (Article III "d[oes] not require ... that

the plaintiff bet the farm, so to speak, by taking the violative action."). Furthermore, the Court specifically explained that there is no bright line test for determining the existence of an actual controversy. *Id.* at 127 ("*Aetna* and the cases following it do not draw the brightest of lines between declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not."). Indeed, this Court in *MedImmune* did not enunciate any specific factors that would tend to establish an actual controversy, much less articulate an "affirmative act" requirement.

This Court made clear that to establish subject matter jurisdiction, the declaratory judgment plaintiff need only satisfy the case-or-controversy requirements of Article III—standing and ripeness. *MedImmune*, 549 U.S. at 128 & n.8. The doctrines of standing and ripeness are pragmatic and look to the totality of circumstances surrounding a particular dispute:

> [T]he question in each case is whether the facts alleged, under ***all the circumstances***, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Id. at 127 (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (emphasis added). Thus, the Federal Circuit's singular focus on an "affirmative act" plainly contravenes *MedImmune*'s and its predecessors' consideration of "all the circumstances" when analyzing whether Article III's case or controversy requirement has been satisfied in the context of a declaratory judgment action.

Here, when considered together, all the circumstances demonstrate that an actual controversy existed at the time ITI filed its declaratory judgment action:

- A member of KCI's Executive Committee confirmed that the odds were 100% that KCI would sue if ITI launched a foam-based, NPWT device, which ITI made clear it intended to do (*supra* at 8-9);

- KCI had publicly articulated its corporate policy to aggressively enforce its patents in its 10-K filings, as well as its belief that its patents have broad applicability to NPWT devices (C.A.A. 192);

- KCI had previously sued all of its primary competitors in the chronic wound care market that had offered NPWT devices (*supra* at 5);

- KCI was aware of both of ITI's FDA submissions based upon discussions at KCI's regular Competitive Intelligence meetings (*supra* at 9);

- Two key KCI decision-makers, including a member of KCI's Executive Committee, had confirmed that KCI was not interested in a business relationship with ITI (*supra* at 7-9); and

- ITI was only days away from launching its new product, having received FDA approval, successfully completed clinical evaluations, entered into non-disclosure agreements with prospective purchasers and investors, and pre-marketed the device to prospective purchasers (C.A.A. 536-37, 1307).

Under these facts, there can be no doubt that, from the onset, ITI faced the *in terrorem* choice that the Declaratory Judgment Act was designed to relieve.

The Court should grant this petition to correct the Federal Circuit's failure to adhere to *MedImmune* and its disregard of the *MedImmune* Court's rejection of any affirmative act requirement for establishing declaratory judgment subject matter jurisdiction.

3. The Federal Circuit's Affirmative Act Rule Conflicts with Other Circuits' Correct Application of the Declaratory Judgment Subject Matter Jurisdiction Jurisprudence of this Court.

The Federal Circuit's application of the "affirmative act" rule for establishing declaratory judgment subject matter jurisdiction diverges from the well-traveled paths of other Circuits in applying the fundamental jurisdictional principles of *MedImmune* and its predecessors. In *MedImmune*, this Court reaffirmed the "all circumstances" standard first announced in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941). This Court also explained that Congress intended the Declaratory Judgment Act to "ameliorate" the declaratory judgment plaintiff's "dilemma" posed by "cho[osing] between abandoning his rights or risking prosecution," and accordingly, that such plaintiffs need not "bet the farm" before seeking declaratory relief. *MedImmune*, 549 U.S. at 129, 134. In sharp contrast to these fundamental principles and their application by other Circuits, the Federal Circuit's "affirmative act" rule prevents a declaratory judgment plaintiff from clarifying his

rights when a patentee stops just short of an explicit threat of litigation.

In *Dewey & Almy Chemical Co. v. American Anode, Inc.*, 137 F.2d 68 (1943), the Third Circuit applied *Maryland Casualty* to resolve a strikingly similar patent dispute. Dewey engaged in certain commercial methods of producing rubber goods from latex that potentially infringed two of Anode's patents. *Id.* at 68-69. Anode had previously sued other manufacturers who used similar methods for infringement of the same patents. *Id.* at 70. Dewey sought a declaration of non-infringement under the Declaratory Judgment Act. However, the district court dismissed the suit for lack of jurisdiction, noting that Anode had not accused Dewey of infringement or threatened litigation. *Id.* In fact, American Anode purportedly did not even know that Dewey potentially infringed its patents until it read its complaint for declaratory relief. *Id.*

Reversing the district court, the Third Circuit disregarded Anode's lack of any affirmative act towards Dewey, explaining that "the fact that Anode had never made any direct threat to sue Dewey ... is not conclusive of the problem." *Id.* at 70. Instead, the Third Circuit focused on the patent owner's long history of infringement litigation as an "economic weapon." *Id.* In concluding that an actual controversy did indeed exist, the Third Circuit reasoned that the patent owner's prior litigation, which asserted a broad scope for its patent claims, constituted "equally effective notice to whom it may concern that they practise [sic] [the patented process] at their peril." *Id.* at 71.

The Fifth Circuit has also concluded that an affirmative act is not a predicate for declaratory judgment subject matter jurisdiction. In *Venator Group Specialty, Inc. v. Matthew / Muniot Family, LLC*, 322 F.3d 835 (5th Cir. 2003), a tenant sought declaratory relief three years before the termination of a lease to clarify whether it was required to make expensive alterations to the leased property. The terms of that lease obligated the tenant to make the alterations if the landlord so requested in writing sixty days before the lease terminated. The district court dismissed the declaratory judgment complaint for lack of jurisdiction, concluding that there was no controversy until the landlord requested the alterations to be made—an affirmative act. But the Fifth Circuit reversed, explaining that the district court must "necessarily assess the likelihood that future events will occur" and determine "whether an injury that has not yet occurred is significantly likely to happen to justify judicial intervention." *Id.* at 840. The Fifth Circuit held that the controversy was sufficiently immediate and real because the circumstances made it "very likely" that the landlord would invoke the challenged lease provision. *Id.* at 839-41.

Relying upon *Maryland Casualty*, the Ninth Circuit recently concluded that subject-matter jurisdiction existed over an employee's suit for declaratory relief from discriminatory practices, despite the fact that the employer had not specifically directed an affirmative act towards the employee. *Hulteen v. AT&T Corp.*, 498 F.3d 1001, 1004 n.1 (9th Cir. 2007) (en banc), *rev'd on other grounds*, 129 S. Ct. 1962 (2009). The Ninth Circuit reasoned that a sufficiently real and immediate controversy existed based on the employer's behavior

towards other employees. Thus, the employee faced a "real and immediate threat" of discrimination "given [her employer's] truculent refusal to credit [other] employees for their pre-PDA pregnancy leave in its benefits calculations." *Id.* Other Ninth Circuit cases have reached similar results. *See, e.g., Yahoo! Inc. v. La Ligue Contre Le Racisme Et L'Antisemitisme*, 433 F.3d 1199, 1211 (9th Cir. 2006) (per curiam) (declaratory challenge to enforceability of French court injunction was constitutionally ripe even though the French government had not sought to enforce it in the United States); *see also NBA v. SDC Basketball Club, Inc.*, 815 F.2d 562, 566 (9th Cir. 1987) (rejecting formulation of case and controversy requirement that would require the NBA to actually impose a fine or sanction before a declaratory judgment action could accrue, calling it the "type of Damoclean threat that the Declaratory Judgment Act is designed to avoid").

The Federal Circuit's "affirmative act" rule perpetuates the Hobson's choice that the Declaratory Judgment Act was intended to remedy. It permits a defendant to constrain otherwise lawful conduct while safely knowing its target cannot seek redress through declaratory relief. This result conflicts with other Circuits' faithful application of this Court's Article III jurisprudence set forth in *MedImmune* and its predecessor *Maryland Casualty*. Accordingly, the Court should grant the petition.

B. *MedImmune* and Its Predecessors Make Clear that an Actual Controversy Exists Even If a Patentee Purportedly Could Not Have Sued the Declaratory Judgment Plaintiff

The Federal Circuit incorrectly concluded that there was no actual controversy based upon the District Court's finding and KCI's argument that KCI could not have sued ITI for patent infringement at the time ITI filed its declaratory judgment action because KCI had never physically seen ITI's product. 4a ("KCI had not seen any device produced or intended to be produced by ITI ... and KCI had not charged ITI with infringement as to any such device"), 7a ("informal conversations did not constitute a threat of suit ... against a device that had not been seen and evaluated for infringement"). But, as explained above, this Court in *MedImmune* rejected such categorical rules, concluding instead that a declaratory judgment plaintiff need only satisfy the constitutional requirement to show the existence of a real and imminent dispute. 549 U.S. at 127. Moreover, this Court in *MedImmune* and predecessor cases made clear that the existence of an actual controversy is not predicated upon a patentee's ability or intent to bring a cause of action against the declaratory judgment plaintiff.

In abrogating the reasonable apprehension of suit test, this Court in *MedImmune* specifically rejected the argument that a case or controversy cannot exist where a patentee is unable to sue the declaratory judgment plaintiff. *Id.* at 132 n.11. Indeed, the patentee in *MedImmune* argued that declaratory judgment jurisdiction did not exist because the

declaratory judgment plaintiff had continued to pay royalties under a patent licensing agreement, and therefore, the patentee could not have filed suit for patent infringement. *Id.* at 134-35. This Court relied on its previous precedent to show that no such requirement existed, explaining that in *Maryland Casualty*, 312 U.S. at 273, "jurisdiction obtained even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured." *MedImmune*, 549 U.S. at 132 n.11. Similarly, this Court has also made clear that declaratory judgment jurisdiction can exist even if there is no indication that a declaratory judgment defendant intends to file suit. For example, in *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227, 239 (1937), "jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit." *MedImmune*, 549 U.S. at 132 n.11.

This Court should grant this petition to reject any notion that the existence of an actual controversy depends on whether the patentee has the present ability or intent to sue the declaratory judgment plaintiff for patent infringement. Such a requirement could be easily manipulated by patentees. For example, a patentee could delay filing suit in purposeful ignorance of a potentially infringing product and allow significant damages to accrue while the potential infringer would have no recourse to bring a declaratory judgment action. That result would be antithetical to the purpose of the Declaratory Judgment Act—to remove the Damoclean threat of suit by providing a potential infringer with relief from uncertainty and delay regarding its legal rights. A

potential infringer should be able to take the initiative by filing a declaratory judgment complaint to resolve its conflict with a patentee without waiting for the patentee to initiate an action at a time and in a manner that the patentee deems suitable. *MedImmune*, 549 U.S. at 132 n.11.

C. District Courts Do Not Have Unfettered Discretion to Dismiss Declaratory Judgment Actions Where an Actual Controversy Exists

The Declaratory Judgment Act provides that a district court "***may*** declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a) (emphasis added). Although the Declaratory Judgment Act confers upon a district court a measure of discretion in deciding whether to hear a declaratory judgment action, that discretion is not unbounded. Here, the District Court abused its discretion in dismissing ITI's declaratory judgment complaint, and the Federal Circuit erred in affirming the discretionary dismissal.

This Court has not spoken directly on the issue of the proper exercise of discretion in dismissing a declaratory judgment action involving a purely federal question, or more specifically, a patent dispute. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 290 (1995) ("We do not attempt at this time to delineate the outer boundaries of ... discretion in other cases, for example, cases raising issue of federal law."); *MedImmune*, 549 U.S. at 136 ("leav[ing] the equitable, prudential, and policy arguments in favor of ... a discretionary dismissal" in a declaratory judgment patent action to the district court in the first instance). However, the

legislative history and jurisprudence of this Court and the Courts of Appeals provide a framework for assessing the District Court's discretionary dismissal.

The Report of the Senate Judiciary Committee analyzing the then soon-to-be-enacted Declaratory Judgment Act stated that courts would have discretion not to entertain a declaratory judgment "'if it will not finally settle the rights of the parties.'" *Aetna Cas. & Sur. Co. v. Quarles*, 92 F.2d 321, 324 (4th Cir. 1937) (quoting Senate Report No. 1005, 73d Cong., 2d Sess. (May 10, 1934)). Over the years, this Court has delineated the bounds of discretion to dismiss a declaratory judgment action. As an initial matter, a court "cannot decline to entertain such an action as a matter of whim or personal disinclination." *Pub. Affairs Assocs., Inc. v. Rickover*, 369 U.S. 111, 112 (1962). This Court has affirmed courts' exercise of discretion to dismiss declaratory judgment actions that would involve "futile or premature interventions," *Public Service Comm'n v. Wycoff Co.*, 344 U.S. 237, 243 (1952), or where a dispute could "better be settled in the proceeding pending in [a] state court," *Brillhart v. Excess Ins. Co.*, 316 U.S. 495 (1942). And, certain Courts of Appeals have analyzed discretionary dismissals under the rubric of whether the declaratory judgment action in question would serve the objectives of the Declaratory Judgment Act. *See, e.g.*, *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008) ("[W]hether hearing the case would serve the objectives for which the Declaratory Judgment Act was created.") (internal quotation omitted); *Quarles*, 92 F.2d at 324 ("[D]iscretion should be liberally exercised to effectuate the purposes of the statute and thereby afford relief from uncertainty and insecurity.").

In this case, the District Court summarily concluded that the exercise of its jurisdiction would not serve the objectives of the Declaratory Judgment Act: "I am not convinced that the objectives of the Declaratory Judgment Act are being served by allowing such a plaintiff to plead uncertainty and delay." 14a. Significantly, that conclusion cannot be squared with the opening sentence of the District Court's opinion that "[t]his case arguably presents a situation meant to be addressed by the Declaratory Judgment Act," and the District Court failed to provide any explanation for its decision. 18a. Thus, the District Court's unexplained discretionary dismissal plainly falls into the category of "whim[sical]" dismissal, *Rickover*, 369 U.S. at 112, and therefore constitutes an abuse of discretion.

The District Court's discretionary dismissal of ITI's declaratory judgment patent counts also clearly conflicts with the objectives of the Declaratory Judgment Act. On the eve of the commercial launch of its first product, ITI was faced with the choice of accruing potential damages or abandoning its activities. Indeed, one of KCI's Executive Committee members handicapped the odds of suit at "100%" if ITI launched its foam-based NPWT product, and KCI had already sued every competitor that dared to enter the market with such a product. *Supra* at 15-16. This Court explained that such an *in terrorem* choice is precisely what the Declaratory Judgment Act was designed to prevent. *MedImmune*, 549 U.S. at 134 (recognizing that "[a] plaintiff need not 'bet the farm, or ... risk treble damages" before seeking a declaration of its actively contested legal rights). A declaratory judgment plaintiff, such as ITI, should not be blocked from removing a litigious patentee's Damoclean threat

of suit by a district court's whimsical exercise of discretionary dismissal.

The Federal Circuit erred by effectively failing to review the discretionary dismissal. As an initial matter, the Federal Circuit merely restated the District Court's rationale for the discretionary dismissal—ITI's pre-suit conduct somehow did not comport with the objectives of the Declaratory Judgment Act—and concluded that the rationale was not an abuse of discretion. 12a-13a. The Federal Circuit also failed to review the District Court's discretionary dismissal under its own controlling precedent.

The Federal Circuit previously ruled that in deciding whether to exercise its discretion, a district court must determine "whether hearing the case would serve the objectives for which the Declaratory Judgment Act was created." *Micron*, 518 F.3d at 902 (internal quotation omitted). Indeed, the Federal Circuit explained that if the objectives of the Act are served, dismissal is "rarely" appropriate. *Id.* But the District Court and the Federal Circuit erroneously focused on ITI's pre-suit conduct, which has no bearing on whether the declaratory judgment action was consistent with the purposes of the Act. Had the Federal Circuit applied the correct standard, it should have reversed the District Court's discretionary dismissal.

Judge Friendly famously announced that "[j]udicial and academic statements with respect to the discretion of the trial court under the Federal Declaratory Judgment Act can be described as 'curiouser and curiouser.'" Henry J. Friendly, *Indiscretion About*

Discretion, 31 Emory L.J. 747, 778 (1982). More than two decades later, the legal standard for discretionary dismissals of declaratory judgment actions involving patent disputes remains just as murky. As noted above, the Court has not spoken directly on this issue. Therefore, the Court should grant this petition to clarify the correct legal standard for analyzing discretionary dismissals of declaratory judgment complaints involving patent disputes.

VII.
CONCLUSION

For the foregoing reasons, this Court should grant ITI's petition for writ of certiorari.

Respectfully submitted,

Jonathan G. Graves
Counsel of Record
Justin P.D. Wilcox
Scott A. Cole
COOLEY LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive, Suite 1600
Reston, VA 20190
(703) 456-8000
jgraves@cooley.com

August 24, 2010

APPENDIX

APPENDIX

TABLE OF CONTENTS

Appendix A:	Opinion, United States Court of Appeals for the Federal Circuit (April 1, 2010)	1a
Appendix B:	Memorandum Order, In the United States District Court for the District of Delaware (November 5, 2008)	17a
Appendix C:	Report and Recommendation Regarding Defendants' Motion to Dismiss, In the United States District Court for the District of Delaware (July 14, 2008)	22a
Appendix D:	Order denying rehearing, United States Court of Appeals for the Federal Circuit (May 26, 2010)	44a

APPENDIX A

United States Court of Appeals for the Federal Circuit

No. 2009-1085

[Decided April 1, 2010]

INNOVATIVE THERAPIES, INC.,

Plaintiff–Appellant,

v.

KINETIC CONCEPTS, INC., KCI LICENSING, INC., and KCI USA, INC.,

Defendants–Appellees.

Appeal from the United States District Court for the District of Delaware in case no. 07-CV-589, Judge Sue L. Robinson

Jonathan G. Graves, Cooley Godward Kronish, LLP, of Reston, VA, argued for plaintiff-appellant. With him on the brief was Justin P.D. Wilcox.

Erik R. Puknys, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Palo Alto, CA, argued for defendants-appellees. With him on the brief were Wendy A. Herby; Donald R. Dunner and Don O.

Burley, of Washington, DC. Of counsel on the brief were R. Laurence Macon and Karen Kroesche Gulde, Akin Gump Strauss Hauer & Feld LLP, of San Antonio, TX.

Before MICHEL, Chief Judge, NEWMAN and PROST, Circuit Judges.

NEWMAN, Circuit Judge.

Innovative Therapies, Inc. ("ITI") appeals the judgment of the United States District Court for the District of Delaware, dismissing ITI's declaratory judgment action against Kinetic Concepts, Inc. ("KCI") based on absence of an actual controversy within the contemplation of the Declaratory Judgment Act.[1] We affirm the dismissal.

DISCUSSION

The five patents at issue are United States Patent Nos. 4,969,880; 5,645,081; 5,636,643; 7,198,046; and 7,216,651, all owned by the defendant KCI or exclusively licensed to KCI from the assignee Wake Forest University. The patents relate to medical devices for negative pressure wound therapy, used in treatment of chronic wounds. Several of the inventors are scientists at Wake Forest University in Winston–Salem, North Carolina.

The declaratory plaintiff ITI was established in 2006 by several former employees of KCI, in

---

[1] *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, No. 07–589–SLR/LPS, 2008 WL 4809104 (D. Del. Nov. 5, 2008).

conjunction with Dr. Paul Svedman, a surgeon who had worked in the field of negative pressure wound therapy. On September 25, 2007 ITI filed this suit for declaration that the five patents are invalid and/or not infringed by a device that ITI planned to offer for sale "on or about October 1, 2007," called the Svedman Wound Treatment System. KCI moved to dismiss for lack of declaratory jurisdiction, stating that it had not seen the ITI device, had not examined it for possible infringement of any KCI patent, and had not accused ITI of infringement. ITI responded that sufficient adverse interests existed to entitle it to adjudication, citing the liberalized criteria for declaratory actions as established by the Supreme Court in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S.Ct. 764, 166 L.Ed.2d 604 (2007). ITI identified several factors that when considered together, as required by *MedImmune*'s totality of the circumstances test, were stated by ITI to establish declaratory jurisdiction.

I

In dismissing the complaint, the district court observed that the mere existence of an adversely held patent does not suffice to establish adverse legal interests, and that the circumstances cited by ITI did not establish declaratory jurisdiction at the time the complaint was filed. On appeal ITI again argues that a confluence of three factors, taken together, established the existence of a controversy of "sufficient immediacy and reality," the words of *MedImmune*, to warrant declaratory jurisdiction. These factors are (1) ITI's representations to the FDA, (2) ITI's phone calls to KCI executives, and (3) KCI's patent enforcement history.

(1) ITI's representations to the FDA

ITI had obtained expedited pre-marketing approval of the Svedman device based on its representations to the FDA that the Svedman device has the "same technological characteristics" as KCI's previously approved wound therapy device and other FDA-approved devices that KCI has charged with infringement. ITI stated that such expedited approval, obtained pursuant to § 510(k) of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360(k), demonstrated the reasonableness of ITI's belief that KCI would regard the Svedman device as infringing KCI's patents. ITI stated that it learned through discovery that KCI was aware of ITI's filings with the FDA. ITI thus argued that KCI had sufficient knowledge of ITI's Svedman device, even before its introduction to the market, to suggest that KCI might have been preparing to sue ITI for infringement.

KCI responded in the district court that at the time ITI filed this declaratory action KCI had not seen any device produced or intended to be produced by ITI, that no such device had been sold or offered for sale, and that KCI had not charged ITI with infringement as to any such device. KCI argued that ITI's representations that the Svedman device has the "same technological characteristics" as a patented product did not establish infringement of any KCI patent.

The district court accepted that ITI had requested and received regulatory approval for a product that it intended to place on the market. Although "meaningful preparation" to take infringing action may suffice for declaratory jurisdiction in some

circumstances, *see Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881 (Fed. Cir. 2008), representations to a third person about "technological characteristics" do not establish a justiciable controversy with the patentee. Although the parties disputed the extent of knowledge that KCI had about ITI's filings with the FDA, we agree with the district court that even if KCI knew of ITI's representations to the FDA, this knowledge of itself did not create a controversy within the contemplation of the Declaratory Judgment Act.

(2) ITI's phone calls to KCI executives

ITI placed its strongest reliance on two telephone calls from ITI, arguing that statements made by KCI employees during these phone conversations were sufficient to demonstrate the existence of a justiciable controversy.

On September 12, 2007 ITI's Chief Technology Officer, David Tumey, who had previously been employed at KCI as Director of Research and Development, telephoned his former colleague Michael Girouard, KCI's Director of Marketing. Another ITI employee who also was a former KCI employee, Mark Meents, participated in the call. The parties agree that during the call Tumey described the Svedman device and asked Girouard to predict KCI's response to ITI's planned launch of this product. Tumey and Meents stated that Girouard responded: "KCI will act aggressively. You know that." Tumey and Meents also stated that Girouard qualified his statement by saying that KCI would sue only "if it first determined that the product infringed the KCI patents." Tumey stated that Girouard said that he was aware of one of ITI's two 510(k) filings with the FDA, but Girouard

disputed this aspect of the conversation. The district court stated that it accepted ITI's version of this conversation for the purpose of determining whether to accept declaratory jurisdiction.

On September 17, 2007 Tumey telephoned another former colleague, Michael Burke, Senior Vice President of Manufacturing at KCI. Tumey knew that Burke planned to retire at the end of September. The parties stated that after discussing Burke's imminent retirement, Tumey described the Svedman device and asked Burke how he thought KCI would react when ITI introduced this device. Tumey stated that Burke responded that KCI would "aggressively go after us . . . particularly if it is foam-based." Tumey stated that when he asked Burke if the odds were "100%" that KCI would sue, Burke responded "100% no doubt about it," and stated that any product that "scratches the surface of our patents" would be the subject of a lawsuit. Tumey stated that he asked about the possibility of peacefully coexisting, and that Burke said there was "no way to coexist."

ITI argued that these telephone conversations established that a controversy existed with respect to patent infringement by the devices that ITI intended to market. KCI argued that these phone calls, initiated by ITI in the guise of friendly conversations, did not constitute a threat of legal action by KCI as to products they had not seen and had not reviewed for infringement. KCI stated that neither Girouard nor Burke had authority to decide on his own whether KCI would conduct infringement litigation, although ITI disputed this point.

The district court described these phone calls as a "sub rosa" effort to create jurisdiction "by initiating telephone conversations to employees of the patentee who were not in decision-making positions and who were not informed of the real purpose behind the conversations." The court found that these phone calls, made to former colleagues who had not seen and had not evaluated ITI's device, produced impromptu responses, not an assertion of patent rights.

ITI argues on this appeal that a justiciable controversy was indeed created by KCI's statements during ITI's telephone calls. ITI states that the district court misunderstood the purpose of the phone calls, and that they were not a subterfuge to establish jurisdiction, but an effort to clear the air as to the product ITI was about to launch. KCI responds that Tumey phoned his ex-colleagues under cover of friendship, without revealing his true purpose and without knowing whether those persons had knowledge of the structure of the ITI device and any basis for threatening an infringement suit. KCI argues that ITI sought to obtain indirect evidence of a controversy without subjecting itself to the possibility of suit. Thus KCI argues that its employees' impromptu responses cannot be deemed to be charges of infringement or other indications of a real and immediate controversy within the cognizance of the Declaratory Judgment Act.

The district court found that these informal conversations did not constitute a threat of suit for patent infringement against a device that had not been seen and evaluated for infringement of any patent. We agree that the indirection reflected in these conversations did not produce a controversy of such

"immediacy and reality" as to require the district court to accept declaratory jurisdiction. *See SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1378 (Fed. Cir. 2007).

(3) KCI's patent enforcement history

The third aspect on which ITI relied was KCI's history of litigation to enforce its patents. ITI argued that KCI's known enforcement of these patents against others should be given weight in evaluating the telephone statements of the KCI executives. KCI responded that although it indeed enforces its legal rights, it had not seen any ITI device, no ITI device had been sold, and no accusation of infringement or threat of suit had been made, either in these phone conversations or in any other way. KCI stressed that ITI's assertion to the FDA that similar products had received FDA approval does not equate to a statement that ITI's Svedman device infringes any KCI patent. *See CardioVention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007) ("Courts have repeatedly refused to allow FDA 510(k) notification of substantial equivalence as admission of infringement in patent cases.").

The district court found that KCI's history of litigation against others, and general propensity to enforce its legal rights, did not establish an actual controversy between KCI and ITI over a device that KCI had not seen and evaluated. Although *MedImmune* held that a reasonable apprehension of suit for infringement is not always required to establish declaratory jurisdiction, the particular circumstances must be considered. In *MedImmune* there was no apprehension of suit for infringement

because the challenger was already licensed under the patent and continued to pay royalties, even as the challenger sought to adjudicate the obligation to pay royalties. The Court held that the licensee did not have to terminate or breach the license in order to challenge the licensor's position and that the licensee did not have to risk loss of the license in order to obtain judicial review of its obligations under the license. However, *MedImmune* did not hold that a patent can always be challenged whenever it appears to pose a risk of infringement. *See SanDisk,* 480 F.3d at 1380–81 ("In the context of conduct prior to the existence of a license, declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee.").

Thus while prior litigation is a circumstance to be considered in assessing the totality of circumstances, the fact that KCI had filed infringement suits against other parties for other products does not, in the absence of any act directed toward ITI, meet the minimum standard discussed in *MedImmune. See Prasco, LLC v. Medicis Pharm. Corp.,* 537 F.3d 1329, 1341 (Fed. Cir. 2008) (noting that "prior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy," but concluding that no controversy was shown). The holding of *Micron Tech., Inc. v. Mosaid Techs., Inc.,* 518 F.3d 897, 901 (Fed. Cir. 2008), is not otherwise, for in *Micron* the patentee had not only litigated the patents against others, but also had sent several threatening letters to the declaratory plaintiff. The specific facts of each case

must be considered, in deciding whether a declaratory action is warranted.[2]

Subsequent events

ITI pointed to events that occurred after its declaratory judgment complaint was filed but before the district court's decision on the motion to dismiss, and argued that the presence of a controversy at the time of filing was confirmed by KCI's later suits against ITI, after KCI had inspected the Svedman device. On December 4, 2007 ITI permitted KCI to inspect the Svedman device and provided KCI with copies of the User Manual and Instructions. On January 2, 2008 KCI filed suit in Texas state court against ITI and three of its employees who had previously been employed by KCI, with counts including breach of confidentiality agreements and misappropriation of trade secrets. On January 10, 2008 KCI and Wake Forest University filed a patent infringement suit in the Middle District of North Carolina, based on acts of alleged infringement that occurred in High Point, North Carolina.

The district court held that subsequent events could not change the fact that no actual controversy existed at the time the original complaint was filed. The court observed that the existence of justiciable controversy is determined as of the time of the filing of the complaint, citing *GAF Building Materials Corp. v.*

---

[2] ITI has moved the court to take judicial notice of other litigation involving KCI and third parties. The motion is granted, although these aspects do not affect our affirmance of the district court's judgment.

Elk Corp. of Dallas, 90 F.3d 479, 483 (Fed. Cir. 1996) ("[L]ater events may not create jurisdiction where none existed at the time of filing."). *See Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007) ("The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since.").

On January 25, 2008 ITI filed an Amended Complaint, adding counts based on KCI's conduct subsequent to the filing of ITI's original complaint. The Amended Complaint included new counts for false advertising and unfair competition in violation of the Lanham Act, based on KCI's criticism of the Svedman device to potential customers, and requesting a declaration of ITI's unencumbered right to use and sell the Svedman device. KCI then filed another motion to dismiss for lack of declaratory judgment jurisdiction, or in the alternative to transfer the case to the Middle District of North Carolina. The district court observed that ITI's Amended Complaint was actually a "supplemental" complaint, which is the proper pleading when a party seeks to add issues based on events that occurred after the filing of the original complaint. *See* Fed. R. Civ. P. 15(d) (providing for "supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented"). The district court observed that ITI had not sought leave to file this pleading, as is required by Rule 15, but in the interest of "completeness" the court treated the Amended Complaint as if it were an authorized supplemental pleading.

The district court found that the later acts by KCI, including the filing of an infringement suit, showed that an actual controversy existed as of that later date. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993) ("If . . . a party has actually been charged with infringement of the patent, there is, necessarily, a case or controversy adequate to support jurisdiction."). However, we agree with the district court that these acts after the filing of ITI's original complaint did not establish that an actual controversy existed at that earlier time. *See Grupo Dataflux v. Atlas Global Group, L.P.*, 541 U.S. 567, 570–71, 124 S.Ct. 1920, 158 L.Ed.2d 866 (2004) ("It has long been the case that the jurisdiction of the court depends upon the state of things at the time the action was brought.").

ITI argues that the district court erred when it evaluated whether a controversy existed at the time the original complaint was filed. ITI states that the date of the Amended Complaint provided the operative time, citing this court's recent decision in *Prasco*, 537 F.3d at 1337 ("As the district court accepted Prasco's Amended Complaint, it is the Amended Complaint that is currently under consideration, and it is the facts alleged in this complaint that form the basis of our review."). *Prasco* indeed focused on the allegations of the complaint as amended, but it did not thereby change the rule that unless there was jurisdiction at the filing of the original complaint, jurisdiction could not be carried back to the date of the original pleading. The district court observed that to hold otherwise "would invite a declaratory judgment plaintiff in a patent case to file suit at the earliest moment it conceives of any potential benefit to doing so, confident that it will either draw an infringement suit in

response (thereby retroactively establishing jurisdiction over their first-filed declaratory judgment suit) or will suffer no adverse consequence other than having its suit dismissed." *Innovative Therapies,* No. 07-589-SLR/LPS, 2008 WL 2746960, at *10 (D. Del. July 14, 2008).

Federal Rule of Civil Procedure 15(c) does not treat events that post-date the original pleading as if they had occurred at an earlier time. The district court so recognized when it treated the Amended Complaint as a supplemental, rather than amended, pleading. We discern no error in the district court's conclusion that ITI's supplemental complaint did not establish an actual controversy at the time of the original pleading, and that jurisdiction based on subsequent events did not relate back to the filing date of the initial complaint. KCI points out that its suits in the Middle District of North Carolina and in state court in Texas were filed before the supplemental complaint. *See, e.g., Electronics for Imaging, Inc. v. Coyle,* 394 F.3d 1341, 1347 (Fed. Cir. 2005) ("We apply the general rule favoring the forum of the first-filed case, unless considerations of judicial and litigant economy, and the just and effective disposition of disputes, requires otherwise."); *Genentech, Inc. v. Eli Lilly & Co.,* 998 F.2d 931, 937 (Fed. Cir. 1993) ("The general rule favors the forum of the first-filed action, whether or not it is a declaratory action.").

II

The district court also held that the case should be dismissed in the exercise of the court's discretion. *See Wilton v. Seven Falls Co.,* 515 U.S. 277, 282, 115 S.Ct. 2137, 132 L.Ed.2d 214 (1995) ("[D]istrict courts possess

discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites."). The district court explained that ITI had used a ploy to attempt to generate jurisdiction through informal phone calls to past colleagues, and that this strategy did not comport with the purposes of the Declaratory Judgment Act. The district court did not abuse its discretion in observing that "where (as here) a declaratory judgment plaintiff was not willing to make its concerns of record pre-suit, I am not convinced that the objectives of the Declaratory Judgment Act are being served by allowing such a plaintiff to plead uncertainty and delay." The district court also observed that all of the issues raised by ITI were subject to resolution in the cases pending in Texas and North Carolina.

ITI argues that the district court abused its discretion. However, the discretion afforded to district courts to administer the declaratory judgment practice is broad. *See id.* at 287, 115 S.Ct. 2137 (noting the "unique breadth" of district courts' declaratory discretion); *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1288 (Fed. Cir. 2007) ("If a district court's decision is consistent with the purposes of the Declaratory Judgment Act and considerations of wise judicial administration, it may exercise its discretion to dismiss (or stay) the case."); *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 813–14 (Fed. Cir. 1996) (same). We discern no abuse of discretion in the district court's discretionary decision on the facts and circumstances of this case.

III

ITI also argues that the district court committed legal error because it failed to apply the "convenience factors" of choice of forum, discussed in *Micron* as relevant to the exercise of declaratory jurisdiction. In *Micron* an infringement suit was filed the day after a declaratory judgment action was filed in a different forum, and this court ruled that the reasons whereby the district court dismissed the earlier-filed declaratory suit were insufficient. This court stated that "in cases such as this with competing forum interests, the trial court needs to consider the 'convenience factors' found in a transfer analysis under 28 U.S.C. § 1404." 518 F.3d at 902–03.

Although *Micron* did not hold that forum convenience is the dominant consideration relevant to the court's exercise of discretion in every case, the convenience factors of this case do not weigh against the district court's dismissal. ITI is incorporated in Delaware, but its principal place of business is in Maryland. KCI is incorporated in Texas and has its principal place of business in Texas, the situs of the asserted state law violations. Co-defendants KCI Licensing and KCI USA are incorporated in Delaware, but have their principal places of business in Texas. The Middle District of North Carolina is the home of Wake Forest University and the inventors of four of the five patents in suit, and is the forum in which the sole act of infringement is stated to have occurred. ITI's unfair competition count in its supplemental complaint is based on conduct that is asserted to have occurred in the Middle District of North Carolina. ITI has not stated that any party has any significant business operations in Delaware, nor that any witness

resides in Delaware, nor that any conduct relevant to any aspect of the parties' dispute occurred there. We hence reject ITI's argument that the convenience of the forum requires retaining the action in Delaware, for the undisputed facts are incompatible with such a conclusion.

CONCLUSION

The district court did not clearly err in its findings concerning the factors on which ITI relied to support declaratory jurisdiction, and did not abuse its discretion in its decision to dismiss the declaratory action including the supplemental complaint. The dismissal is affirmed.

AFFIRMED.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civ. No. 07-589-SLR/LPS

[Filed November 5, 2008]

INNOVATIVE THERAPIES, INC.,	)
	)
Plaintiff,	)
	)
v.	)
	)
KINETIC CONCEPTS, INC., KCI LICENSING, INC. and KCI USA, INC.,	)
	)
Defendants.	)

MEMORANDUM ORDER

At Wilmington this 5th day of November, 2008, having reviewed the Report and Recommendation issued July 14, 2008, and the objections filed in connection therewith;

IT IS ORDERED that the Report and Recommendation is adopted and the case dismissed,[1] consistent with the following reasoning:

1. **Legal standard.** This case arguably presents a situation meant to be addressed by the Declaratory Judgment Act, that is, plaintiff (a company getting ready to market a new medical device that "has essentially the same technological characteristics" as a "predicate device" previously approved by the FDA) suspects an adverse reaction from the manufacturer of the "predicate device," which device is covered by a portfolio of patents. As characterized by the Federal Circuit, the Declaratory Judgment Act exists to provide such a company with "relief from uncertainty and delay regarding its legal rights." *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987). The problem, of course, is determining when there exists a substantial enough dispute between an alleged infringer and the patentee to satisfy the "case or controversy" requirement of Article III of the Constitution.

2. The United States Supreme Court has recognized in this regard that

> [t]he difference between an abstract question and a "controversy" contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy.

---

[1] Defendants' motion to dismiss (D.I. 44) is granted.

Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941); *see also Sony Electronics, Inc. v. Guardian Media Technologies, Ltd.*, 497 F.3d 1271, 1283 (Fed. Cir. 2007). Indeed, while acknowledging the need for a bona fide dispute between parties, the Supreme Court has fashioned its standard for determining the existence of subject matter jurisdiction in the broadest sense:

> Our decisions have required that the dispute be "definite and concrete, touching the legal relations of parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.". . . [Therefore,] "the question in each case is whether the facts alleged, **under all the circumstances**, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

Medimmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 S. Ct. 764, 771 (2007) (citations omitted) (emphasis added). Rather than articulate a particular evidentiary standard, the Federal Circuit has followed suit and simply held that, "[i]n short, 'all the circumstances' must show a controversy." *Micron Tech., Inc. v. Mosaid Technologies, Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008).

3. The Federal Circuit has recognized in this regard that the "more lenient legal standard" pronounced by the Supreme Court in *Medimmune* "facilitates or enhances the availability of declaratory judgment

jurisdiction in patent cases" that "could occasion a forum-seeking race to the courthouse between accused infringers and patent holders." *Micron*, 518 F.3d at 902. As in this case, where defendants/patentees subsequently filed a patent infringement suit against plaintiff in North Carolina, to some extent "the parties in this dispute are really just contesting the location and right to choose the forum for their inevitable suit." *Id.* at 902-903.

4. **Analysis.** Plaintiff at bar has argued that its declaratory judgment action should not be dismissed because defendants were actively investigating plaintiff and its FDA-approved device months before the instant declaratory judgment action was filed,[2] defendants had previously filed patent infringement lawsuits against competitors, and plaintiff was told (through telephone conversations between employees of plaintiff and defendants) that defendants would sue if plaintiff launched an infringing product. Defendants contend in response that they could not have brought suit against plaintiff without examining plaintiffs product, something plaintiff would not permit.[3]

5. Taking all of plaintiff's allegations as true, I am not convinced that a potential infringer should be able

---

[2] *See* D.I. 71, ex. D.

[3] Plaintiff contends that, had it been allowed follow-up jurisdictional discovery from defendants, it would have uncovered more evidence of an intent to sue. While such requests for discovery should rarely be denied, since it is undisputed that no such intent was ever communicated to plaintiff, the question remains whether jurisdiction should be based on non-public evidence that can be gathered only after suit is actually filed.

to create subject matter jurisdiction *sub rosa* (in this case, by initiating telephone conversations to employees of the patentee who were not in decision-making positions and who were not informed of the real purpose behind the conversations). To put the point differently, although I agree with plaintiff that "an affirmative act" by the patentee directed toward the declaratory judgment plaintiff may not always be required,[4] nevertheless, where (as here) a declaratory judgment plaintiff was not willing to make its concerns a matter of record pre-suit, I am not convinced that the objectives of the Declaratory Judgment Act are being served by allowing such a plaintiff to plead uncertainty and delay. *Cf. SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1385 (Fed. Cir. 2007) (Bryson, concurring) (a declaratory judgment plaintiff can send "a 'put up or shut up' response" to a patentee's suspected investigative or licensing efforts; any response by the patentee would expose it to a declaratory judgment action).[5] Therefore, even if subject matter jurisdiction were established to my satisfaction, I agree that the case should be dismissed in the exercise of my discretion. *See Micron*, 518 F.3d at 902.

/s/ Sue L. Robinson
United States District Judge

---

[4] In my view, the broad standard established by the Supreme Court should not be anchored in such a narrow paradigm.

[5] I acknowledge that such a holding will keep the odds in the race to the courthouse in a patentee's favor.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 07-589-SLR-LPS

[Filed July 14, 2008]

INNOVATIVE THERAPIES, INC.,	)
	)
Plaintiff.	)
	)
v.	)
	)
KINETIC CONCEPTS, INC., KCI LICENSING, INC. and KCI USA, INC.,	)
	)
Defendants.	)

REPORT AND RECOMMENDATION REGARDING DEFENDANTS' MOTION TO DISMISS

This patent case has been referred to me for a Report and Recommendation pursuant to 28 U.S.C. § 636(b). (D.I. 7) Plaintiff seeks: (1) a declaration of noninfringement and invalidity of Defendants' patents related to medical devices used in negative pressure wound therapy; (2) a declaration that Defendants made false and misleading statements about Plaintiffs wound treatment device in violation of the Lanham

Act, 15 U.S.C. § 1125(a), along with money damages and an injunction against further false statements; and (3) a declaration that Plaintiff is the sole owner of its own wound treatment device and any related intellectual property.

Presently before me is Defendants' motion to dismiss Plaintiff's first amended complaint due to a purported lack of subject matter jurisdiction. (D.I. 44) In the event that I find that this Court possesses subject matter jurisdiction, Defendants move to transfer this action to the Middle District of North Carolina, pursuant to 28 U.S.C. § 1404(a). *Id.* In the further alternative, Defendants move to dismiss or stay Count XII of the amended complaint (which seeks a declaratory judgment of ownership of intellectual property) on the ground that it mirrors a cause of action Defendants already filed in Texas state court. *Id.* For the reasons stated below, I recommend that Defendants' motion to dismiss be GRANTED.

JURISDICTIONAL AND PROCEDURAL BACKGROUND[1]

The Parties

Plaintiff Innovative Therapies, Inc. ("Innovative") is a Delaware corporation with its principal place of business in Hunt Valley, Maryland. (D.I. 36 ¶ 1) Innovative was co-founded in 2006 by the professor and inventor Dr. Paul Svedman along with a former

---

[1] Except where describing certain declarations made part of the record by Defendants, this Background takes as true the allegations contained in Innovative's amended complaint.

officer and several former employees of Defendants. (D.I. 36 ¶ 15) Innovative develops and produces therapies in the area of patient wound care. *Id.*

Defendant Kinetic Concepts. Inc. is a Texas corporation with a principal place of business in San Antonio, Texas. (D.I. 36 ¶ 2) Its co-defendants, KCI Licensing. Inc. and KCI USA, are its wholly-owned subsidiaries. (D.I. 36 ¶¶ 3-4) KCI Licensing and KCI USA are Delaware corporations with principal places of business in San Antonio. *Id.* (Defendants are referred to collectively hereinafter as "KCI.")

KCI is a medical products designer and manufacturer that has sold several negative pressure wound therapy devices under the registered trademark V.A.C.® (D.I. 36 ¶ 9) KCI's wound therapy devices are covered by a portfolio of patents, including the five patents in suit, U.S. Patents No.: (1) 4,969,880 ("the '880 patent"), (2) 5,636,643 ("the '643 patent"), (3) 5,645,081 ("the '081 patent"), (4) 7,198,046 ("the '046 patent"), and (5) 7,216,651 ("the '651 patent"). *Id.* KCI is the assignee of the '880 patent (D.I. 48 at 4) The remaining four patents in suit are owned by Wake Forest University. (D.I. 36 ¶¶ 10-14) KCI holds the exclusive, worldwide right to make, use, lease, and sell products incorporating the inventions covered by the Wake Forest patents. *Id*

Innovative Develops The Svedman Wound Treatment System

In 2007, Innovative finalized development of a negative pressure wound therapy device named the Svedman™ Wound Treatment System ("Svedman"). (D.I. 36 ¶ 16) The Svedman is purportedly based upon

Dr. Paul Svedman's work in the field of wound therapy in the late 1970s and early 1980s. (D.I. 48, Vogel Decl. ¶ 12) Innovative describes its system as offering wound care equivalent to KCI's V.A.C.® at a significantly lower cost and in an easier-to-use form. (D.I. 48 at 3)

Innovative made two 510(k) submissions to the Food and Drug Administration (FDA) relating to the Svedman, using a streamlined procedure allowing an applicant to claim that its new medical device "has essentially the same technological characteristics" as a "predicate device" previously approved by the FDA. (D.I. 36 ¶ 17) On March 30, 2007, Innovative submitted a 510(k) premarket notification to the FDA for a product it called the "ANTLIA II Suction Pump System," which utilizes negative pressure to promote wound healing. (D.I. 36 ¶ 18; D.I. 48 Ex. A) Innovative claimed the Bluesky Medical Versatile 1 Wound Vacuum System and the Medela Invia Healing System as "predicate devices" to the ANTLIA II. *Id.* The makers of these predicate devices, Bluesky and Medela, have each been sued by KCI for patent infringement.[2]

On May 8, 2007, Innovative submitted a 510(k) premarket notification to the FDA for a product called the "ANTLIA I Wound Irrigation System," which promotes wound healing through a combination of negative pressure and irrigation. (D.I. 36 ¶ 19: D.I. 48

---

[2] *See Kinetic Concepts, Inc., et al. v. Medela AG,* No. 07-187 (E.D. Tex.) (filed May 15, 2007) (pending) and *Kinetic Concepts, Inc., et al. v. Bluesky Med. Corp.*, No. 03-832, 2007 WL 1113002 (W.D. Tex. April 4, 2007).

Ex. A) Innovative claimed KCI's V.A.C.® as a predicate device, asserting that the ANTLIA I had "essentially the same technological characteristics" as the V.A.C.® (D.I. 36 ¶ 19) The FDA approved both of Innovative's submissions. (D.I. 36 ¶¶ 18-19; D.I. 48 Ex. A)

Events Leading To Filing Of The Initial Complaint

Prior to the filing of Innovative's initial complaint on September 25, 2007, Innovative Chief Technology Officer (and former KCI Director of Research and Development) David Tumey contacted two of his former colleagues at KCI "to assess the potential for avoiding litigation by consummating a business relationship between the parties." (D.I. 48 at 6) It is undisputed that on September 12, 2007, Tumey spoke by telephone to KCI Director of Marketing Michael Girouard about the possibility of litigation between Innovative and KCI over the Svedman device. (D.I. 48, Meents Decl. & Tumey, Decl.; D.I. 11, Girouard Decl.)[3] It is further undisputed that Mark Meents, another former KCI employee and Innovative co-founder, also participated in the call to Girouard. (D.I. 48, Meents Decl. & Tumey Decl.; D.I. 11, Girouard Decl.)

The parties disagree as to whether Girouard had the apparent authority to speak to KCI's intentions regarding a possible patent infringement suit. According to Girouard's affidavit, he has been KCI's Director of Marketing for 14 years and, as Tumey

---

[3] KCI relies on declarations filed in connection with its motion and briefing seeking dismissal of Innovative's original complaint. (D.I. 45 at 3, n.3)

would have understood from their long working relationship at KCI, Girouard was "not involved in making decisions regarding whether KCI will sue anyone." (D.I. 11, Girouard Decl. ¶¶ 1-3). Tumey states, to the contrary, that he believed that "as a KCI Director, Mr. Girouard would be in a position to understand KCI's current institutional attitude toward patent enforcement against competitive products." (D.I. 48, Tumey Decl. ¶ 7)

The affidavits further reveal a dispute as to Girouard's (and KCI's) information about Innovative and Innovative's products. Girouard states that he had never heard of Innovative before Tumey's and Meents' call. (D.I. 11, Girouard Decl. ¶ 11) He "was not aware of Mr. Tumey's two 510(k)s or his product before our conversation." *Id.* In contrast, Tumey states that Girouard admitted during the course of their phone conversation "that he was aware of one, but not two of the 510(k)s" Innovative had submitted to the FDA. (D.I. 48, Tumey Decl. ¶ 8) According to Tumey, Girouard stated that "his awareness of one of the 510(k)s came from KCI's regular 'Competitive Intelligence' meetings." *Id.* Tumey's recollection is supported by Meents' affidavit.[4] (D.I. 48, Meents Decl. ¶¶ 4-6)

Both sides agree that during the telephone call Tumey described the Svedman device and asked Girouard to predict KCI's response to Innovative's planned launch of its product. Girouard recalls that he

---

[4] Innovative has submitted Tumey's and Meents' "handwritten contemporaneous notes" from the call in support of their declarations. (D.I. 48 Exs. A & C)

responded that KCI would view the Svedman and, if it determined that it infringed a KCI patent, "would probably take legal action." (D.I. 11: Girouard Decl. ¶ 10) Girouard further states that he thinks he "told Mr. Tumey that this would not be my determination in any event." *Id.* Tumey, on the other hand, recalls that Girouard replied to his question by stating, "KCI will act aggressively. You know that." (D.I. 48, Tumey Decl. ¶ 12) Tumey's recollection is again supported by Meents. (D.I. 48, Meents Decl. ¶ 7) Tumey and Meents both recall that Girouard predicted KCI would take legal action against Innovative, although both also state that Girouard qualified his opinion by adding that KCI would only sue "if it first determined that the product infringed the KCI patents." (D.I. 48, Meents Decl. ¶ 8 & Tumey Decl. ¶ 13) Neither Tumey nor Meents remembers Girouard telling them that Girouard would not be the one to determine KCI's course of action. (D.I. 48, Meents Decl. ¶ 9 & Tumey Decl. ¶ 14)

Less than a week later, on or about September 17, 2007, Tumey telephoned his former supervisor, KCI Senior Vice President of Manufacturing and Executive Committee member Michael Burke, again in order to discuss a potential business relationship between the parties and assess the likelihood of an infringement suit by KCI. (D.I. 48, Tumey Decl. ¶ 15; D.I. 10, Burke Decl. ¶ 6)[5] No one else was on the call. Burke states that prior to the conversation he had never heard of Innovative and did not know that Tumey was working in the field of wound care. (D.I. 10 Burke Decl. ¶ 11)

---

[5] Burke subsequently retired from KCI on September 30, 2007. (D.I. 10. Burke Decl. ¶ 1)

Once again, the parties differ as to whether Tumey could have attributed to the KCI officer he called the authority to speak for KCI on legal matters. Burke states that his primary responsibility at KCI was to oversee manufacturing operations and, thus, he had no involvement in deciding whether or not KCI would sue a competitor. *Id.* Tumey responds that he believed that as a vice president and member of KCI's Executive Committee, Burke was positioned to "provide a realistic assessment of the KCI mind-set regarding enforcement of its patents against competitive products." (D.I. 48, Tumey Decl. ¶ 16)

After describing the Svedman, Tumey asked Burke how he thought KCI would react to the product's release. Burke states that he replied he was "in no position to speak for KCI, especially on legal issues," and went on to repeat a number of times that he "was not in the loop" on such matters. (D.I. 10, Burke Decl. ¶ 8) Burke further states that in response to Tumey's question whether he was "100% certain that KCI would sue" Innovative if the Svedman was released, Burke told Tumey that he was "out of the loop" and did not know how KCI would respond. (D.I. 10, Burke Decl. ¶ 9) Tumey, however, states that in answer to his question of whether the likelihood of suit was 100%, Burke replied, "100% no doubt about it," and added that any new product that "scratches the surface of [KCI's] patents" would be the subject of a KCI lawsuit. (D.I. 48, Tumey Decl. ¶ 19)[6] Tumey denies that Burke

---

[6] Innovative has submitted Tumey's "handwritten contemporaneous notes" evidently taken during the call as well as a typed summary he prepared shortly after the conversation. (D.I. 48, Tumey Decl. Exs. D & E)

ever said he was not in a position to speak for KCI or that Burke "once, let alone repeatedly", stated that he was 'not in the loop'" or made "equivalent statements suggesting that he had any doubts that KCI would act in the manner that he described." (D.I. 48, Tumey Decl. ¶ 22) Tumey further declares that when he attempted to explore whether the parties "could peacefully coexist," Burke immediately dismissed the possibility. (D.I. 48. Tumey Decl. ¶ 20) Burke's affidavit does not comment on this point.

Filing Of The Original Complaint

On September 25, 2007, Innovative filed its original complaint against KCI in this Court, seeking a declaratory judgment of noninfringement and invalidity of each of KCI's five patents underlying the V.A.C.® (D.I. 1) KCI moved to dismiss the complaint on the ground that this Court lacks jurisdiction over its subject matter. (D.I. 8)

Innovative Offers The Svedman For Sale

Innovative made its first offer for the sale of a Svedman device on September 27, 2007, (D.I. 18) The first Svedman was sold during the first week of October 2007. *Id.*

Events Subsequent To The Filing Of The Initial Complaint

On December 4, 2007, before briefing was complete on KCI's motion to dismiss the original complaint, innovative allowed representatives from KCI to inspect its Svedman device and provided KCI with copies of its Users Manual and Instructions, pursuant to

settlement negotiations. (D.I. 36 ¶ 30) On January 2, 2008, KCI filed suit in Texas state court against Innovative and three of its executives (Richard Vogel, David Tumey, and Mark Meents) who had formerly worked for KCI. (D.I. 36 ¶ 36 & Ex. F) KCI's Texas suit claims Innovative and its executives breached KCI confidentiality agreements and misappropriated KCI trade secrets. On January 10, 2008, KCI and Wake Forest University brought a second action against Innovative, this one for patent infringement in the Middle District of North Carolina. (D.I. 36 ¶ 50 & Ex. H) The North Carolina suit alleges that Innovative infringed three of the patents (the '643, '081, and '651) at issue in the instant action. (D.I. 36 ¶ 51)

On January 25, 2008, Innovative filed its first amended complaint in this Court, with updated factual allegations reflecting KCI's actions in Texas state court and the Middle District of North Carolina. (D.I. 36) The amended complaint also adds two counts alleging false advertising/unfair competition and seeking a declaratory judgment that Innovative is the sole and exclusive owner of the Svedman and related intellectual property.

On January 30, 2008, KCI withdrew its motion to dismiss the original complaint. (D.I. 37) On March 12, 2008, KCI filed the instant motion to dismiss Innovative's amended complaint for lack of subject matter jurisdiction. (D.I. 44) In the alternative, KCI requests that this action be transferred to the Middle District of North Carolina, where KCI's infringement suit is currently pending. *Id.*

LEGAL STANDARDS

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of jurisdiction over the subject matter. *See Samsung Elecs. Co. v. ON Semiconductor Corp.*, 2008 WL 900979, at *3 (D. Del. Apr. 3, 2008). Motions brought under Rule 12(b)(1) may present either facial or factual challenges to a court's subject matter jurisdiction.

> In reviewing a facial challenge under Rule 12(b)(1), the standards relevant to Rule 12(b)(6) apply. In this regard, the Court must accept all factual allegations in the Complaint as true, and the Court may only consider the complaint and documents referenced in or attached to the complaint. *Gould Electronics, Inc., v. United States,* 220 F.3d 169, 176 (3d Cir. 2000). [In contrast, however,] [i]n reviewing a factual challenge to the Court's subject matter jurisdiction, the Court is not confined to the allegations of the complaint, and the presumption of truthfulness does not attach to the allegations in the complaint. *Mortensen v. First Fed Sav. & Loan,* 549 F.2d 884, 891 (3d Cir. 1997). Instead, the Court may consider evidence outside the pleadings, including affidavits, depositions and testimony, to resolve any factual issues bearing on jurisdiction. *Gotha v. United States,* 115 F.3d 176, 179 (3d Cir. 1997).

Id.

Here, because KCI attacks the factual basis for jurisdiction, the Court is not required to accept

Innovative's allegations as true, but is instead "free to weigh evidence outside the pleadings to resolve factual issues bearing on jurisdiction and to satisfy itself as to the existence of its power to hear the case." *UD Technology Corp. v. Phenomenex, Inc.*, 2007 WL 28295, at *2 (D. Del. Jan. 4, 2007). Indeed, "[f]ederal courts are under an independent obligation to examine their own jurisdiction." *Pfizer, Inc. v. Elan Pharmaceutical Research Corp.*, 812 F. Supp. 1352, 1356 (D. Del. 1993) (internal quotation marks and citations omitted). "Once the Court's jurisdiction is challenged, the plaintiff bears the burden of proving that jurisdiction exists." *Samsung*, 2008 WL 900979, at *3.

DISCUSSION

I. There Was No "Actual Controversy" At The Time Innovative Filed Its Original Complaint

For declaratory judgment jurisdiction pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, to be present, there must be an "actual case or controversy" between the parties. *Medimmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 778 (2007). The case or controversy requirement in a declaratory judgment action is satisfied only if an actual case or controversy exists "in the constitutional sense." *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227, 240 (1937). A justiciable controversy in the constitutional sense "must be definite and concrete, touching the legal relations of parties having adverse legal interests. It must be a real and substantial controversy admitting of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Id.* at 240-41.

In *Medimmune,* the Supreme Court held that jurisdiction over a declaratory judgment action requires a dispute that is:

> definite and concrete, touching the legal relations of parties having adverse legal interests. It must be a real and substantial controversy admitting of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts. . . . Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

127 S.Ct. 764 at 771 (emphasis added; internal citations omitted).

With *Medimmune,* the Supreme Court rejected what had been the Federal Circuit's "reasonable apprehension of suit test" for determining whether jurisdiction existed in a declaratory judgment patent suit.[7] In the wake of the *Medimmune* decision, the

---

[7] Prior to the Supreme Court's decision in *Medimmune,* the Federal Circuit applied a two-prong test for determining declaratory judgment jurisdiction, finding the existence of an actual controversy where there was both "(1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with

Federal Circuit has acknowledged that "[t]he difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would he possible, to fashion a precise test for determining in every case whether there is such a controversy." *Sony Electonics, Inc. v. Guardian Media Technologies, Ltd.*, 497 F.3d 1271, 1283 (citation omitted).

The Federal Circuit's recent decisions have, however, provided some guidance in elaborating on the *Medimmune* standard. In *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, the Court held that a "controversy is ripe if the question presented is . . . entirely or substantially a question of law and postponing a decision would work a substantial hardship on the challenging party." 482 F.3d 1330, 1337 (Fed. Cir. 2007) (internal citation and quotation marks omitted). Most significantly, in *SanDisk Corp v. STMicroelectronics, Inc.*, the Federal Circuit explained:

> [D]eclaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative

---

the intent to conduct such activity." *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004) (internal quotation marks omitted). Following *Medimmune*, the Federal Circuit has recognized that the "reasonable apprehension of suit test is no longer a necessary criterion for declaratory judgment jurisdiction." *Micron Tech, Inc. v. Mosaid Tech, Inc.*, 518 F.3d 897, 902 (Fed Cir. 2008).

> act by the patentee. But Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do. . . . We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights.

480 F.3d 1372, 1380-81 (Fed Cir. 2007) (emphasis added; internal citation omitted).

Innovative's original complaint identifies the following evidence that, Innovative asserts, establishes subject matter jurisdiction under *Medimmune*'s "all the circumstances" standard as of the date this action was filed: KCI's "consistent[] and aggressive[]" history of litigation seeking to enforce its patent rights with respect to the V.A.C.® device; KCI's 10-K report filed with the Securities and Exchange Commission, which notes that if the company is "unsuccessful in protecting and maintaining our intellectual property, particularly our rights under the Wake Forest patents, our competitive position would be harmed:" KCI's awareness that Innovative received FDA approval for its own negative pressure wound therapy device, based on 510(k) submissions that cited as predicate devices either KCI's V.A.C.® or products of competitors that KCI had sued for patent infringement; and the

telephone statements from KCI officers "expressly warn[ing] [Innovative] of the likelihood that they [KCI] will sue [Innovative] for patent infringment." (D.I. 1 ¶¶ 18- 20)

Missing from this recitation is any allegation of an "affirmative act" by KCI directed toward Innovative that could meet the requirement set out by the Federal Circuit in *SanDisk*. Innovative argues that no "affirmative act" is required to establish declaratory judgment jurisdiction because, according to Innovative, neither the Supreme Court in *Medimmune* nor the Federal Circuit in *SanDisk* or any other case has established a requirement of an affirmative act. (D.I. 57 at 19-21) I disagree.

Innovative's first argument essentially asks me to tell the Federal Circuit it misunderstood the Supreme Court's *Medimmune* decision. But Federal Circuit precedent governs district courts with respect to subject matter jurisdiction issues in patent suits, *see Minnesota Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 672 (Fed Cir. 1991), so the Federal Circuit's interpretation of *Medimmune* is binding on this Court. Innovative's second argument is also incorrect. *SanDisk* speaks repeatedly of a patentee having to commit an "affirmative act" or "take[] a position or "assert[] rights under a patent" in order for there to be declaratory judgment jurisdiction. 480 F.3d at 1380-81. This thrice-stated requirement is, I think, just that: a requirement that *action* be taken by the patentee in order for an actual controversy between the parties to exist. While it is true that *SanDisk* says declaratory judgment jurisdiction "generally" will not arise without some affirmative act by the patentee, *id.*, the Federal Circuit did not explain on what basis this general

requirement would be excused and I see no reason to treat the instant case as *sui generis* in that regard.

Innovative's related claim that the Federal Circuit has not required an affirmative act in cases subsequent to *SanDisk* (D.I. 57 at 21) is also unpersuasive. These cases, while not invoking the "affirmative act" language per se, are fully in keeping with the *SanDisk* requirement since both cases plainly involved obvious affirmative acts by the patentee. *See Micron*, 518 F.3d at 898 (patentee "sent a warning letter strongly suggesting that [plaintiff] should license [patentee's] technology" and three follow-up letters); *Sony*, 497 F.3d at 1274-76 (patentee sent plaintiff series of letters alleging infringement, including detailed charts listing each patent claim alleged to be infringed).

In the alternative, Innovative contends that the statements made by Girouard and Burke on the phone to Tumey constitute the requisite affirmative act. (D.I. 57 at 22) However, even taking as true Tumey's and Meents' version of the phone calls Tumey placed to KCI's Girouard and Burke, the KCI officers' statements do not satisfy the affirmative act requirement. Girouard merely stated that KCI was aware of one of Innovative's two 510(k) submissions and had discussed this submission at a KCI Competitive Intelligence meeting; he also expressed his opinion that KCI would "act aggressively" upon Innovative's launch of the Svedman. (D.I. 48, Tumey Decl. ¶¶ 8, 11-13 & Meents Decl. ¶ 8) As Tumey details, however, Girouard was speaking only of possibilities (i.e., what KCI would do if it concluded the Svedman infringed), not affirmatively asserting rights on KCI's behalf. Tumey declares: "When I asked Mr.

Girouard whether this meant that KCI would sue if we launched this product [i.e., the Svedman], he responded that KCI would take legal action, but clearly indicated that such action would take place only after KCI determined that the product infringed the KCI patents." (D.I. 48, Tumey Decl. ¶ 13) (emphasis added)

The situation is similar with Burke. Burke rejected the possibility that KCI and Innovative "could peacefully coexist." (D.I. 48, Tumey Decl. ¶ 20) He answered Tumey's question as to whether the chances of a KCI infringement suit against Innovative were 100% by stating, "100% no doubt about it." (D.I. 48, Tumey Decl. ¶ 19) But, according to Tumey, Burke also "clarified this point by adding that any product that 'scratches the surface of our patents' would be the subject of a lawsuit." *Id.* While Burke's remarks were less equivocal than Girouard's, they nevertheless left a degree of contingency that render them something less than an "affirmative act" of the type required by *SanDisk*. This is especially so because at the time Burke made these comments, neither be nor anyone at KCI had seen the Svedman or measured it against KCI's patents. As far as the record reveals, no one at KCI had reached even a tentative conclusion as to whether the Svedman infringed KCI's patents.

Therefore, even assuming that Girouard and Burke had at least apparent authority even to speak for KCI on patent-related issues, I conclude that, under all the circumstances, the comments made by KCI's officers on calls initiated by Innovative do not constitute KCI taking an affirmative act or "tak[ing] a position" or even "assert[ing] rights under a patent." *SanDisk*, 480 F.3d at 1380-81; *see also Baker Hughes Oilfield*

Operations, Inc. v. Reedhycalog UK, Ltd., 2008 WL 345849 at *2-3 (D. Utah Feb. 6, 2008) (dismissing action seeking declaratory judgment of noninfringement, invalidity, and unenforceability of patents due to lack of "affirmative act" by patentee, even though patentee had sent plaintiff numerous letters evidencing that patentee was evaluating possible infringement litigation against plaintiff). It follows that there was no actual controversy between Innovative and KCI as of the date Innovative filed its original complaint and, thus, declaratory judgment jurisdiction was lacking at that time.

II. Events Occurring Subsequent To The Filing Of The Original Complaint Cannot Cure The Previous Lack Of An Actual Controversy

The allegations in Innovative's amended complaint do set out affirmative acts by KCI of the kind required to demonstrate the existence of an actual controversy between the parties. For instance, the amended complaint includes the allegations that KCI sued Innovative for patent infringement relating to the Svedman device. (D.I. 36 ¶¶ 36-53) Innovative insists that even if the original complaint is deficient, the amended complaint cures any defects.

Innovative is incorrect. It is well-settled that the burden is on the declaratory judgment plaintiff to "establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." *Benitec Australia, Ltd v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed Cir. 2007). "[L]ater events may not create jurisdiction where none existed at the time of filing" of the complaint. *GAF Building Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479,

483 (Fed Cir. 1996) (internal citation omitted). Indeed, the Supreme Court's recent statement regarding diversity jurisdiction is equally applicable here: "It has long been the case that the jurisdiction of the court depends upon the state of things at the time of the action brought. This time-of-filing rule is hornbook law (quite literally) taught to first-year law students in any basic course on federal civil procedure." *Grupo Dataflux v. Atlas Global Group, L.P.*, 541 U.S. 567, 570-71 (2004) (internal quotation marks, footnote, and citation omitted).

Nevertheless, Innovative insists that "a supplemental pleading that includes additional facts that occurred after the filing of the original pleading may cure a jurisdictional defect." (D.I. 58 at 1)[8] Although Innovative cites several cases in supposed support of this proposition, *see, e.g.*, D.I. 48 at 10-11; D.I. 58 at 1-2: none of these cases -- nor any others the Court has located – involve courts permitting premature (i.e., pre-actual controversy) declaratory judgment patent actions to be saved by a supplemental

---

[8] Innovative never sought leave to file a "supplemental" complaint - to add allegations of events occurring after the filing of the original complaint, *see* Fed. R. Civ. Proc. 15(d) - and instead filed an "amended" complaint - which should only have added allegations of events that had occurred prior to the filing of the original complaint, *see Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, 2006 WL 2375035, at *4 (D. Del. Aug. 16, 2006). Whether I can dismiss on that ground is an issue I do not reach. Instead, I treat Innovative's filing as if it were a proper supplement instead of an amendment.

pleading incorporating events that occurred after the filing of the original complaint.[9]

By contrast, KCI has cited multiple cases, including one from this district, in which courts have rejected precisely what Innovative proposes be done here. *See Fairplay Elec. Cars, LLC v. Textron Innovations, Inc.*, 431 F.Supp.2d 491, 493 (D. Del. 2006) (holding that declaratory judgment plaintiff could not rely on letter from patentee - implicitly alleging infringement - to create jurisdiction since letter was sent after plaintiff had filed suit); *see also Baker Hughes*, 2008 WL 345849, at *3 ("Events that transpired after filing cannot operate to create jurisdiction at the time of

---

[9] *See Mathews v. Diaz*, 426 U.S. 67, 75 & n.9 (1976) (permitting, pursuant to 28 U.S.C. § 1653, declaratory judgment plaintiff in social security case to supplement complaint to add that he had filed claim for benefits before filing suit; Supreme Court later explained, in *Newman-Green, Inc. v. Alfonzo-Larrain*, 490 U.S. 826, 831 (1989), that § 1653 only permits supplemental pleadings to fix "incorrect statements about jurisdiction that actually exists, and not defects in the jurisdictional facts themselves"); *Snyder v. Pascack Valley Hospital*, 303 F.3d 271, 276 (3d Cir. 2002) (articulating general principle that an "amended complaint supersedes the original version in providing the blueprint for the future course of a lawsuit"); *Black v. Secretary of Health and Human Services*, 93 F.3d 781 (Fed Cir. 1996) (holding that plaintiff pressing claim for compensation under National Childhood Vaccine Injury Act could supplement petition to add allegation he had incurred the requisite threshold expenses within statute of limitations period, even if some of those expenses were incurred after filing of initial petition); *Intrepid v. Pollack*, 907 F.2d 1125, 1129 (Fed Cir. 1990) (finding, in case in which jurisdiction had existed at and since time of filing of original complaint, that district court abused its discretion in not permitting plaintiff to supplement complaint to include challenge to post-complaint finding of International Trade Administration).

filing."); *Monsanto Co. v. Syngenta Crop Protection, Inc.*, 2008 WL 294291, at *7 (E.D. Mo. Jan. 31, 2008) (same). I agree with KCI's cases, as they are consistent with the "hornbook law" cited above. Indeed, to reach the contrary conclusion, and allow a supplemental pleading to cure a jurisdictional defect that existed at the time the original complaint was filed, would invite a declaratory judgment plaintiff in a patent cases to file suit at the earliest moment it conceives of any potential benefit to doing so, confident it will either draw an infringement suit in response (thereby retroactively establishing jurisdiction over their first-filed declaratory judgment suit) or will suffer no adverse consequence other than having its suit dismissed.

Accordingly, an actual controversy between Innovative and KCI needs to have existed at the time Innovative filed its original complaint. As previously explained, it did not. That an actual controversy arose shortly after Innovative's original filing does not cure the jurisdictional defect that existed at the time of the original filing. Therefore, subject matter jurisdiction is lacking and Innovative's action should be dismissed.

RECOMMENDED DISPOSITION

For the reasons set forth above, I recommend that Defendants' motion to dismiss be GRANTED.

Dated: July 14, 2008

/s/ Leonard P. Stark
Honorable Leonard P. Stark
UNITED STATES MAGISTRATE JUDGE

APPENDIX D

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2009-1085

[Decided May 26, 2010]

INNOVATIVE THERAPIES, INC.,

Plaintiff–Appellant,

v.

KINETIC CONCEPTS, INC., KCI LICENSING, INC., and KCI USA, INC.,

Defendants–Appellees.

Appeal from the United States District Court for the District of Delaware in case no. 07-CV-589, Judge Sue L. Robinson

ORDER

A petition for rehearing en banc having been filed by the Appellant, and the matter having first been referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on June 2, 2010.

FOR THE COURT,

/s/ Jan Horbaly [LB]
Jan Horbaly
Clerk

Dated: 05/26/2010

cc: Jonathan G. Graves
Donald R. Dunner

INNOVATIVE THERAPIES V KINETIC, 2009-1085 (DCT - 07-CV-589)

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

MAY 26 2010

JAN HOBALY CLERK